

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tramacet® 37.5mg/325mg effervescent tablets

Tramadol hydrochloride/Paracetamol



Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Tramacet is and what it is used for
2. Before you take Tramacet
3. How to take Tramacet
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1. WHAT TRAMACET IS AND WHAT IT IS USED FOR

Tramacet is used to treat moderate to severe pain when your doctor recommends that a combination of tramadol hydrochloride and paracetamol is needed.

2. BEFORE YOU TAKE TRAMACET

Do not take Tramacet

- if you are hypersensitive or have had an allergic reaction (for instance skin rash, swelling of the face, wheezing or difficulty breathing) to tramadol, paracetamol, sunset yellow (E110) or any of the other ingredients (see section 6) in Tramacet
- in cases of acute alcohol poisoning
- if you are taking sleeping pills, pain relievers or medicines that affect mood and emotions
- if you are also taking medicines called monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the last 14 days before treatment with Tramacet. MAOIs are used in the treatment of depression or Parkinson's disease.
- if you have a severe liver disorder
- if you have epilepsy that is not adequately controlled by your current medicine.

Before you take Tramacet, check with your doctor or pharmacist if you:

- take other medicines containing paracetamol or tramadol
- have liver problems or disease as your eyes and skin may turn yellow, which may suggest jaundice
- have kidney problems
- have severe difficulties in breathing, for example asthma or severe lung problems
- have epilepsy or have already experienced fits or seizures
- have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick)
- are dependent on any medicine (for example morphine)
- take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine
- are going to have an anaesthetic (tell your doctor or dentist that you are taking Tramacet).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor will tell you which medicines are safe to take with Tramacet.

Do not exceed the maximum daily doses of paracetamol or tramadol from this or other medicines.

Do not take Tramacet with MAOIs (see section 'Do not take Tramacet').

Tramacet is not recommended with the following medicines, as it may affect how well they work:

- carbamazepine (a medicine used to treat epilepsy or some types of pain)
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers).

Tramacet may increase the risk of side effects if you also take the following medicines:

- triptans (used for migraine) or selective serotonin re-uptake inhibitors (SSRIs, used for depression). Check with your doctor if you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea.

- tranquilizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), baclofen (a muscle relaxant), medicines used to lower blood pressure, antidepressants or medicines to treat allergies. Check with your doctor if you feel drowsy or feel faint.
- antidepressants, anaesthetics, medicines that affect the state of mind, or bupropion (used to help stop smoking). The risk of having a fit may increase. Your doctor will tell you whether Tramacet is suitable for you.
- warfarin or phenprocoumon (for blood thinning). The effectiveness of such medicines may be altered and bleeding may occur (see section 4).

The effectiveness of Tramacet may be altered if you also take the following medicines:

- metoclopramide, domperidone or ondansetron (medicines used to treat nausea and vomiting/being sick)
- cholestyramine (medicine used to reduce cholesterol in the blood)
- ketoconazole or erythromycin (medicines used against infections).

Taking Tramacet with food and drink

Do not drink alcohol while you are taking Tramacet, as you may feel drowsy.

Pregnancy and breast-feeding

Do not take Tramacet while you are pregnant.

Check with your doctor if you become pregnant during treatment with Tramacet and before taking any further tablets. Do not take Tramacet while you are breast-feeding, as small amounts of tramadol may pass into the breast-milk.

Driving and using machines

If you feel drowsy while taking Tramacet, do not drive, use tools or use machinery.

Important information about some of the ingredients of Tramacet

- The medicinal product contains the colorant sunset yellow (E110) which may cause allergic reactions.
- This medicinal product contains 179.4 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE TRAMACET

Take Tramacet as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take effervescent tablets by dissolving in a glass of drinking water.

Take Tramacet for as short a time as possible and no longer than your doctor has told you.

Adults and adolescents over 12 years:

The recommended dosage is to start with 2 tablets, unless otherwise prescribed by your doctor. If required, further doses may be taken, as instructed by your doctor. The shortest time between doses must be at least 6 hours.

Do not take more than 8 tablets per day.

Your doctor may increase the time between doses if:

- you are older than 75 years
- you have kidney problems
- you have liver problems.

Children under 12 years of age:

- not recommended.

If you think that the effect of Tramacet is too strong (you feel very drowsy or have difficulty breathing) or too weak (you do not have enough pain relief), contact your doctor.

If you take more Tramacet than you should

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.



If you forget to take Tramacet

If you forget to take the tablets, pain is likely to return. Do not take a double dose to make up for forgotten individual doses; simply continue taking the tablets as before.

If you stop taking Tramacet

Generally, there will be no after-effects when treatment with Tramacet is stopped.

Rarely, people who have been using a medicine containing tramadol may become dependent on it, making it hard to stop taking it. If you have been taking Tramacet for some time and want to stop, contact your doctor because your body may have become used to Tramacet. People may:

- feel agitated, anxious, nervous or shaky
- be over active
- have difficulty sleeping
- have stomach or bowel disorders.

Very few people may also get:

- panic attacks
- hallucinations, unusual perceptions such as itching, tingling and numbness
- ringing in the ears.

If you experience any of these complaints after stopping Tramacet, please contact your doctor. Other side effect information is listed in section 4.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tramacet can cause side effects, however not everybody gets them.

Some side effects could be serious. Contact your doctor immediately if any of the following occur:

- rarely cases of skin rash, indicating an allergic reaction, may develop with sudden swelling of the face and neck, difficulties breathing or drop of blood pressure and fainting. If this happens to you, stop treatment. Do not take the medicine again.
- prolonged or unexpected bleeding, from the use of Tramacet with medicines used to thin the blood (e.g. warfarin, phenprocoumon).

Additionally, if any of the following side effects get serious, contact your doctor or pharmacist:

Very common side effects (affecting more than 1 in 10 people treated)

- nausea
- dizziness, drowsiness.

Common side effects (affecting less than 1 in 10, but more than 1 in 100 people treated)

- vomiting (being sick), digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth
- itching, sweating
- headache, shaking
- confusion, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits).

Uncommon side effects (affecting less than 1 in 100, but more than 1 in 1,000 people treated)

- increase in pulse or blood pressure, heart rate or heart rhythm disorders
- difficulty or pain on passing water
- skin reactions (for example rashes, hives)
- tingling, numbness or feeling of pins and needles in the limbs, ringing in the ears, involuntary muscle twitching
- depression, nightmares, hallucinations (hearing, seeing or sensing things that are not really there), memory lapses
- difficulty swallowing, blood in the stools
- shivering, hot flushes, pain in the chest
- difficulty breathing.

Rare side effects (affecting less than 1 in 1,000, but more than 1 in 10,000 people treated)

- fits, uncoordinated movements
- addiction
- blurred vision.

In addition, the following side effects have been reported by people using medicines that contain only tramadol or only paracetamol:

- feeling faint when getting up from a lying or sitting position, slow heart rate, fainting
- changes in appetite
- muscle weakness, slower or weaker breathing
- mood changes, changes in activity, changes in perception
- worsening of existing asthma
- nose bleeds or bleeding gums, which may result from a low blood platelet count.

5. HOW TO STORE TRAMACET

Keep out of the reach and sight of children.

Do not use Tramacet after the expiry date which is printed on the carton and, blister or bottom of the plastic tube.

The expiry date refers to the last day of that month.

Tablets packed in blister strips (aluminium foil):

- Do not store above 25°C.

Tablets packed in plastic tubes:

- Do not store above 30°C.
- After first opening: Keep the container tightly closed in order to protect from moisture.
- Shelf-life after first opening: 1 year, not exceeding the expiry date.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Tramacet contains

The active substances are tramadol hydrochloride and paracetamol.

One (1) tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.

The other ingredients are:

monosodium citrate anhydrous, citric acid anhydrous, polyvinylpyrrolidone, sodium hydrogen carbonate, macrogol 6000, silica colloidal anhydrous, magnesium stearate, orange flavouring (maltodextrin (maize), modified starch (E1450), natural and artificial flavourings)), acesulfame potassium, saccharin sodium, sunset yellow (E110).

What Tramacet looks like and contents of the pack

Tramacet effervescent tablets look off white to slightly rosy coloured with some coloured speckles. The tablets may be available in strips of coated aluminium foil or plastic tubes.

In aluminium strips: packs of 2, 10, 20, 30, 40, 50, 60, 70, 80, 90 or 100 effervescent tablets.

In plastic tubes: packs of 10, 20, 30, 40, 50, 60, 70, 80, 90 or 100 effervescent tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Grünenthal Ltd, Regus Lakeside House, 1 Furzeground Way, Stockley Park East, Uxbridge, Middlesex UB11 1BD, United Kingdom.

Manufacturer:

Grunenthal GmbH, Zieglerstrasse 6, 52078 Aachen, Germany.

Other formats of this leaflet

A service is available to listen to or request a copy of this leaflet in Braille, large print or audio.

• Please call free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

• Product name: TRAMACET

37.5 mg/325 mg effervescent tablets

• Reference number:

PL 21727/0040

This leaflet was approved in:

March 2010